

REMARKS

Claims 4 and 6-10 are pending in the present application. Claims 4 and 6-9 stand rejected under 35 U.S.C. 102(b) as being allegedly anticipated by EP 0743067 to Fukuyama ("Fukuyama"). Claims 4 and 6-10 stand rejected under 35 U.S.C. 103(a) as being allegedly rendered obvious by Nagaki *et al.* Journal of Med. Microbiol., Vol. 38, pages 354-359 (1993) ("Nagaki") in view of EP 0993834 A1 to Hirai ("Hirai"). Applicants respectfully traverse these rejections.

Claims 4 and 6-9 Are Not Anticipated by Fukuyama

On page 3 of the Office Action, the Examiner stated that the adsorbents of Fukuyama comprising compounds such as isocyanates, alcohols, carboxylic acids and derivatives and amines which have log P values not less than 3.00 were the same as the adsorbents recited in claims 4 and 6-9. Applicants respectfully disagree. As stated in Applicants' response of January 5, 2004, Fukuyama merely describes sec-octyl-amine, 6-amino-*n*-caproic acid, 3-amino-1-propene, α -amino-isobutyric acid, aminopyridine, aminobenzenesulfonic acid, diethylenetriamine, triethylenetetramine, tetraethylenepentamine, dipropylenetriamine, *n*-methyldiaminodiethylamine, and polyethyleneimine. These exemplified amino compounds all have log P values of less than 3.00. It should be noted that all amino compounds do not have log P values of 3.00 or more. Some amines have log P values of 3.00 or more, and other amines have log P values of less than 3.00. This is also the case with the other compounds described in Fukuyama--*i.e.* isocyanates, alcohols, carboxylic acids, and derivatives.

Claims 4 and 6-9 specifically recite adsorbents comprising a compound with a log P value of not less than 3.00 that are immobilized on a carrier in order to enhance the property for adsorbing enterotoxins. This enhancement is demonstrated in comparing Example 1 and Example 2 of the present specification. As shown in Table 1, the adsorbing property in Example 1 using *n*-hexadecylamine (log P=7.22) is better than that in Example 2 using *n*-octylamine (log P=2.90), which is outside the range of the invention, as recited in claims 4 and 6-9.

In addition, Fukuyama fails to anticipate claims 4 and 6-9 because Fukuyama does not teach that amino compounds, isocyanates, alcohols, carboxylic acids, and carboxylic acid derivatives are useful in adsorbing enterotoxins. Instead, Fukuyama merely describes the use of urea or thiourea compounds in adsorption of super antigens, which compounds contain a group

capable of forming a hydrogen bond and an aromatic substituent (*See* abstract and page 2, line 3 to page 3, line 11). Fukuyama does not disclose that the urea or thiourea compounds have log P values not less than 3.00. In Fukuyama, the amino compounds, isocyanates, alcohols, carboxylic acids and carboxylic acid derivatives are used as intermediates in the preparation of the urea or thiourea compounds (*See* page 3, lines 40-50; page 4, lines 6-8 and 38-40), not as superantigen adsorbents as erroneously alleged by the Office Action. For at least these reasons, Applicants submit that claims 4 and 6-9 are not anticipated by Fukuyama.

Claims 4 and 6-10 Are Not Rendered Obvious by Nagaki in view of Hirai

Hirai describes a method for adsorbing toxic shock syndrome toxin-1 (TSST-1). However, Hirai does not mention enterotoxins at all, as recited in claims 4 and 6-10.

Nagaki describes a method for adsorbing enterotoxin A but Nagaki does not disclose using adsorbents comprising a compound having a log P value of not less than 3.00, as recited in claims 4 and 6-10. Nagaki only describes that enterotoxins and TSST-1 "are structurally closely related." On page 6 of the Office Action, in response to Applicants prior arguments, the Examiner stated that one of skill in the art would reasonably conclude that TSST-1 and enterotoxins have similar adsorbent properties. However, the Examiner did not specifically point to any support for such a statement either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. Indeed, Nagaki merely describes that enterotoxins and TSST-1 "are structurally closely related" and neither Hirai nor Nagaki mentions the relationship between the adsorbent property of enterotoxins and the adsorbent property of TSST-1. Accordingly, Applicants submit that there is no motivation to a person of skill in the art to replace the adsorbent in the adsorptive method for enterotoxin A of Nagaki with the adsorbent of TSST-1 of Hirai.

The Examiner also indicated that one of ordinary skill in the art would reasonably conclude that TSST-1 as well as enterotoxins can be removed with the same adsorbent with a reasonable expectation of success. However, the Examiner did not state where in Hirai or Nagaki or from what general knowledge of one of ordinary skill in the art this reasonable expectation of success is derived. Concerning the relationship between TSST-1 and enterotoxins, Nagaki merely describes that enterotoxins and TSST-1 "are structurally closely related" and Hirai makes absolutely no comparison of enterotoxins and TSST-1. In the chemical field, it is general knowledge that two compounds that are structurally similar can often have

quite different properties. The Examiner did not seem to take this general knowledge into consideration.

In view of this general knowledge, one of ordinary skill in the art would not have concluded that enterotoxins and TSST-1 have similar adsorbent properties simply from the statement in Nagaki that enterotoxins and TSST-1 are structurally closely related (without in any way describing the relationship between the adsorbent property of enterotoxins and the adsorbent property of TSST-1). Applicants emphasize that structural similarity does not necessarily parallel with adsorbent similarity. If the Examiner continues to maintain this position, then it should specifically be shown where the teaching, suggestion, or motivation is for one of ordinary skill in the art to conclude that enterotoxins and TSST-1 have similar adsorbent properties in order to combine the teachings of Nagaki and Hirai.

Applicants also point out that, for the first time, Applicants demonstrated in the present application that enterotoxin and TSST-1 show similar adsorbent properties on the claimed adsorbent. Nagaki as well as Hirai does not disclose this discovery and one of ordinary skill in the art could not have derived this discovery from the disclosures of Nagaki and Hirai or from the general knowledge at the time the claimed invention was made. Accordingly, Applicants submit that there is no basis for a reasonable expectation of success that the adsorbent for TSST-1 of Hirai can adsorb enterotoxin A in the method of Nagaki. Accordingly, Applicants request withdrawal of the obviousness rejection.

CONCLUSION

It is respectfully submitted that the subject application is now in condition for allowance, which action is earnestly solicited.

The Examiner is invited, upon consideration of the foregoing response, to contact Applicants' representative to discuss any issue that would expedite allowance of the subject application.


The Commissioner is authorized to charge any fees required in connection with this filing, or to credit any overpayments, to Deposit Account 11-0600, referencing Docket No. 12218/1.

Respectfully submitted,

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